510(k) Summary

JAN 18 2011

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone and Fax Number of Applicant

ReVascular Therapeutics, Inc.
766 Palomar Avenue
Sunnyvale, CA 94085
Phone: (408) 617-0770
Fax: (408) 481-9045

B. Contact Person

Nancy Lincé, RAC
Regulatory Affairs Consultant
(650) 759-6186

C. Date Prepared

June 4, 2010

D. Device Name

Trade Name:	RVT CTO Device
Common Name:	Guidewire
Classification Name:	21 CFR §870.1330; Wire, Guide, Catheter
Product Code:	DQX

E. Device Description

The RVT CTO Device is a sterile, disposable, steerable 0.018" OD Guidewire with an Active Tip for penetrating chronic total occlusions and is used with a sterile, disposable, battery-operated Control Unit during a single patient procedure.

The RVT CTO System consists of four (4) components: the RVT CTO Device, Control Unit, Shaping Tool, and the RVT Extension Wire.

1. **RVT CTO Device** *(Guidewire Assembly, Torquer, Motor Housing with integrated Connector Cable)* - The RVT CTO Device consists of a distal 0.018" Guidewire Assembly and a Motor Housing with Connector Cable. The RVT CTO Device is 165 cm in working length and is hydrophilically coated. The RVT CTO Device has a shapeable Distal Tip and the cone-shaped portion of the Active Tip is diamond coated. The distal 3 cm is radiopaque to facilitate visualization under fluoroscopy.

a. Materials used in construction with patient contact: Nitinol, Gold Plated Stainless Steel, Platinum Tungsten, Hydrophilic Coating, Tin, Silver, Nickel, Natural Diamonds

2. **Control Unit** - Pressing the Activation Button allows current to flow from the battery in the Control Unit to the DC Motor within the Motor Housing. Mechanical energy (via rotational torque) is generated and transferred from the DC Motor to the Nitinol Driveshaft located within the stationary hollow Outer Shaft. The Driveshaft turns the Active Tip at the very distal end of the Guidewire Assembly at approximately 13,000 revolutions per minute (RPM) under "no load" conditions. The hollow Outer Shaft remains stationary while the Active Tip rotates independently. In the Active Mode, the RVT Guidewire creates a pathway through the lesion via mechanical rotation. In the "Passive Mode" the operator steers the Guidewire Assembly to seek a path of least resistance through the lesion consistent with standard guidewires.
   a. Materials used in construction with patient contact: none

3. **Shaping Tool** - used to shape the tip of the RVT CTO Device, if desired.
   a. Materials used in construction with patient contact: none

4. **RVT Extension Wire** - Attachment of the RVT Extension Wire to the RVT CTO Device creates an extended guidewire that can be used to exchange a catheter without removing the RVT CTO Device from the artery.
   a. Materials used in construction with patient contact: none

F. Intended Use

The RVT CTO Device is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions. The device is contraindicated for use in carotid arteries. The RVT CTO Device is only intended for use with the RVT Control Unit.

The RVT Extension Wire is designed to extend the RVT CTO Device so that a catheter can be exchanged for another catheter.

G. Predicate Device Comparison

The RVT CTO Device is substantially equivalent to the FlowCardia CROSSER (K072776, K091119) and Baylis Medical RF Tunneler (K051670). The devices have similar components with respect to materials, technological characteristics, intended use, and procedural steps as presented in the following table.

FEATURE	FlowCardia CROSSER System	Baylis PowerWire RF Guidewire (formerly RF Tunneler Wire)	ReVascular Therapeutics RVT CTO Device
510(k) Reference Number	K072776 and K091119	K051670	K101599
Indications for Use	The CROSSER System is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions. The device is contraindicated for use in carotid arteries.	The RF Tunneler Wire is intended to create a channel in totally occluded peripheral vessels 3mm or greater.	The RVT CTO Device is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions. The device is contraindicated for use in carotid arteries.
Design Features	The FlowCardia System consists of reusable electronics (Generator and Transducer) and the single use CROSSER Catheter. The CROSSER Catheter is connected to the electronics by attaching the proximal hub of the CROSSER to the distal end of the Transducer. The Generator converts AC line power into high frequency current. This current is then delivered to piezoelectric crystals contained within the transducer resulting in crystal expansion and contraction. The Transducer horn amplifies the rapid crystal expansion and contraction propagating high frequency mechanical vibration down a Nitinol core wire to the tip of the CROSSER Catheter. This vibrational energy provides mechanical impact which aids in the recanalization of an occluded artery.	The RF Tunneler Wire consists of a core wire surrounded with a polymer insulation. The wire connects to a RF generator at the proximal end via a connector cable, and has an active tip at the distal end to delivery RF energy.	The RVT CTO Device has a Nitinol Outer Shaft and an internal Driveshaft connected to an external distal Active Tip. Active rotational energy is delivered to the distal Active Tip via by the internal Nitinol Driveshaft. The proximal end of the internal Nitinol Driveshaft is connected to an external Motor Housing and a Control Unit.

FEATURE	FlowCardia CROSSER System	Bayliss PowerWire RF Guidewire (formerly RF Tunneler Wire)	ReVascular Therapeutics RVT CTO Device
Main Components	• Core Wire • Catheter • Transducer • Reusable AC Powered Generator • Footswitch	• Nitinol Core w/Insulating Polymer Coating • Proximal Connector Cable • Patient Grounding Pad • Reusable RF Generator and Foot Switch	• Driveshaft with Active Tip • Outer Shaft Assembly • Motor Housing • Control Unit • Shaping Tool • Extension Wire
Energy Type	Mechanical Energy	Radio Frequency Energy	Mechanical Energy
Power Level	20,000 cycles per second	10 - 25 Watts	13,000 revolutions per minute
Mechanism of Action	High frequency current converted into vibrational energy delivered at the distal tip	RF energy delivered at the distal tip	Rotational energy delivered at the distal tip
Shaft Size(s) (OD)	0.043" and 0.061"	0.035"	0.018"
Tip Diameter (OD)	0.043" and 0.061"	0.028"	0.017"
Tip Attributes	Steerable	Steerable, straight, and angled	Steerable, shapeable
Working Length(s)	146 cm and 125 cm	250 cm	165 cm
Radiopacity	Yes	Yes	Yes
Guidewire Exchange Possible	Yes	Yes	Yes
Sterilization Method	Gamma	Ethylene Oxide	Ethylene Oxide
Pyrogen Free	Yes	Yes	Yes
Single Use Only	Yes	Yes	Yes
Meets applicable IEC 60601-1 Testing	Yes	Yes	Yes

The subject and predicate systems provide "active" energy to power the distal Tip of the device through the occlusion. The ReVascular Therapeutics (RVT) CTO Device and its predicates are designed to cross Chronic Total Occlusions (CTO's) in the periphery by providing a means of energy at the distal tip. All the devices are similar in that they convert an external electrical energy source to energy at the device tip. The ReVascular Therapeutics CTO Device and the FlowCardia CTO Device (CROSSER) are designed to cross CTO's in the periphery by providing a means of

mechanical energy at the distal tip and the Baylis PowerWire RF Guidewire System provides radio frequency energy to power the guidewire through the occlusion. Like the PowerWire System, the RVT System uses a guidewire-based platform, while the Crosser is catheter-based. All devices focus energy at the active tip to create channels in the target occlusion. Both the RVT and Baylis devices may be used as standard guidewire systems when used in their "passive" modes.

H. Summary of Performance Data

The RVT CTO Device performance characteristics were evaluated in the following in-vitro bench and in-vivo animal studies:

- Dimensional Verification
- Torqueability
- Torque Strength
- Active Tip Rotation
- Tip Stiffness
- Catheter Compatibility
- Flexibility/Trackability
- Device Advancement
- Friction: Static and Dynamic
- Tip Temperature
- Tensile Testing
- Electrical Safety and Electromagnetic Testing
- Tip Shaping
- Coating Adhesion Integrity
- Support Catheter Removal and Advancement Over Extension
- Coil Integrity
- Packaging Testing
- Shipping Testing
- Sterility Testing
- Shelf Life Testing
- Evaluation of safety and performance of the RVT CTO Device in the porcine model
- Biocompatibility

Results of the non-clinical testing demonstrate that the materials chosen, the manufacturing process, and design of the RVT CTO Device meet the established specifications necessary for consistent performance during its intended use. In addition, the testing demonstrates that the RVT CTO Device does not raise new questions of safety or effectiveness when compared to the predicate devices.

I. Summary of Clinical Data

The RVT CTO Device was the subject of an investigational study, the Re-OPEN Study, a prospective, multi-center, single-arm (non-randomized) study conducted to evaluate the device in the treatment of infrainguinal target vessel occlusions classified angiographically as absolute (100% occlusion with no flow), where no antegrade filling beyond the occlusion was visible.

The purpose of the study was to demonstrate that the RVT CTO Device can safely and effectively facilitate the crossing of chronic total infrainguinal artery occlusions

following demonstration of resistance to crossing with conventional guidewire techniques or prior failed treatment attempt. In addition, this study was intended to evaluate the impact of successfully crossing a CTO and allowing subsequent treatment using interventional methods rather than bypass surgery or medical management alone.

A total of 85 patients were enrolled across 3 medical centers in Europe between January and December 2009. The population in this study was composed of patients who presented with Peripheral Artery Disease who met all eligibility criteria and exhibited any of the following conditions: ABI of less than 1.0, abnormal duplex ultrasound, claudication, leg numbness or weakness, leg rest pain, leg skin color changes or non-healing ulcers of the legs or feet, or previously documented lower extremity artery occlusions. Each patient must have had a prior failed attempt or a concurrent and reasonable attempt (at least 5 minutes) during the procedure to demonstrate resistance to conventional guidewire crossing. The occlusions treated under this protocol were all confirmed to be 100% CTOs that had been in existence for 30 days or greater.

The Primary Safety Endpoint was defined as *freedom from clinical perforation (any perforation requiring treatment) of the index lesion to 30 days.* There were no (0.0%) clinical perforations reported at time of intervention with use of the RVT CTO Device and only 1 (1.2%) patient experienced a clinical perforation as a result of a cutting balloon and was successfully treated with stent placement. No further clinical sequelae were reported. This event was considered by the Clinical Events Committee (CEC) to be unlikely related to the RVT CTO Device with a definite relation to the procedure and a probable relation to a preexisting condition.

All SAEs (Serious Adverse Events) were adjudicated by an independent CEC. In addition, the CEC reviewed all AEs in aggregate to ensure that there were no trends or AEs occurring in greater severity or degree of incidence than anticipated for this patient population. There were no AEs reported that were considered unanticipated in nature, severity or degree of incidence.

The Primary Clinical Efficacy Endpoint, defined as *advancement of the RVT CTO Device through the CTO and subsequent distal guide wire positioning* was achieved in 65 out of 85 cases (76.5%). This allowed subsequent positioning of conventional guide wire(s) distal to the vessel occlusion.

The Primary Performance (Technical Success) Endpoint, defined as *facilitation of crossing the CTO with any guide wire* was achieved in 68 of 85 patients (80%).

In conclusion, the ReOPEN Study provides strong evidence that the RVT CTO Device is safe and effective at facilitating crossing of Chronic Total Occlusions (CTOs) in patients with Peripheral Vascular Disease (PAD) where conventional guidewires have failed. The results demonstrated that the RVT CTO device was able to successfully facilitate crossing in the majority of cases where a conventional guidewire was unsuccessful and use of the RVT CTO did not increase the rate of perforations beyond the rate seen with use of a conventional guidewire.

In addition to the non-clinical testing and descriptive comparisons, the data from the ReOPEN study provide further evidence that use of the RVT CTO Device does not raise new questions of safety or effectiveness when compared to the predicate devices.

J. Summary of Data

Non-clinical testing of the subject device has shown that the RVT CTO Device meets the functional, performance, and design requirements derived from a variety of design inputs; including specifications resulting from examination of the predicate devices, external standards and clinician input. In addition to the non-clinical testing and descriptive comparisons, the data from the ReOPEN study provide further evidence that use of the RVT CTO device does not raise new questions of safety or effectiveness when compared to the predicate devices, as demonstrated by a comparison of the investigational study results reported for the FlowCardio predicate and the subject device. The studies were similar in design, both were prospective clinical studies of 85 patients designed to assess the safety and efficacy of the devices in the treatment of infrainguinal target vessel occlusions classified angiographically as absolute (100% occlusion with no flow), where no antegrade filling beyond the occlusion was visible and following demonstration of resistance to crossing with conventional guidewire techniques. The inclusion/exclusion criteria were the same between the two studies as were the study endpoints and results.

The RVT CTO Device is substantially equivalent to the predicate device for intended use, physical characteristics, anatomical sites, performance, safety characteristics, and labeling. The RVT CTO Device incorporates similar design features, procedural steps, and performance characteristics when compared to the predicate devices. Safety and performance testing, combined with the technical equivalency assessment and clinical study results, demonstrate that the RVT CTO Device performs as intended and does not raise any new issues of safety and effectiveness when compared with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ReVascular Therapies
Ms. Nancy Lincé
766 Palomar Avenue
Sunnyvale, CA 94085

SEP 18 2013

Re: K101599
Trade/Device Name: ReVascular Therapies Chronic Total Occlusion (RVT CTO) Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: January 7, 2011
Received: January 10, 2011

Dear Ms. Lincé:

This letter corrects our substantially equivalent letter of January 18, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K101599

Device Name: RVT CTO Device

Indications for Use:

The RVT CTO Device is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions. The device is contraindicated for use in carotid arteries.

The RVT Extension Wire is designed to extend the RVT CTO Device so that a catheter can be exchanged for another catheter.

Prescription Use X **OR** **Over-The-Counter Use** _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number _____